

# PATENT SPECIFICATION

(11) 1 365 769

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- (21) Application No. 11465/72 (22) Filed 11 March 1972  
(23) Complete Specification filed 9 March 1973  
(44) Complete Specification published 4 Sept. 1974  
(51) International Classification B65D 65/42//B65B 51/10;  
B65D 67/00  
(52) Index at acceptance  
B8C 15A 15C 15E1 21B 24B4 24B6B 24D  
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## (54) IMPROVEMENTS RELATING TO A HEAT SEALED PACKAGE

(71) We, MARDON FLEXIBLE PACKAGING LIMITED, a British Company of P.O. Box 3, Norton Hill Factory, Midsomer Norton, Bath, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed to be particularly described in and by the following statement:—

This invention relates to a heat sealed packaging having opposing base materials which are heat sealed together along marginal portions but can be peeled apart to open the package, at least one of the base materials being paper.

The invention is particularly but not exclusively applicable to heat sealed packages containing disposable surgical instruments, syringes or other articles used in surgery or medicine. Such packages are required to meet a number of conditions, e.g. they must allow their contents to be sterilised after heat sealing, they must retain their contents in a sterilised condition until opened, and they must be openable in such a manner as to permit their contents to be removed without contamination. The last condition is met by providing a peelable heat seal which permits a smooth and clean peeling apart of the opposing base materials of the package.

In this specification the term "neutrally sized" is used to mean sized under neutral conditions with a pH value in the range 7.2 to 8.3 inclusive and using an alkyl ketene dimer as the sizing agent.

According to the invention there is provided a package comprising opposing base materials bonded together along marginal portions by means of a heat sealed adhesive and peelable apart to open the package, wherein one of the base materials is neutrally sized paper as defined above.

Machine glazed paper is paper which has one surface made smooth, for example by drying the paper on a heated polished metal cylinder forming part of a paper-making

machine. The other or unglazed surface of the paper remains relatively rough.

Machine glazed paper has good strength characteristics and can be made to a specified porosity and maximum pore size. Where a package is to be sterilised internally by means of ethylene oxide or a mixture of ethylene oxide and inert gas, the paper base material preferably has a Bendtsen porosity between the limits of 60—120 cc/min. To minimise the risk of bacteria entry into the sealed package, the paper should have a basic weight not less than 50g/m<sup>2</sup>, and preferably not less than 55g/m<sup>2</sup>, whilst the maximum pore size should be not greater than 10 mμm. Maximum pore size may be measured by the method described in "Interpretation of Paper Properties, in Terms of Structure" by Dr H. Corte and Dr O. J. Kallmes, in the Transactions of the Oxford Symposium 1961, "The Formation and Structure of Paper", published by the Technical Section of the British Paper and Board Makers Association (Incorporated), London, E.C.4.

For a gas-sterilisable package it is not necessary for the other base material to be porous. This other base material may be either a film of a thermoplastics material, or a laminate comprising two or more layers of similar or dissimilar plastics material, or a plastics coating upon a porous substrate such as for example a polyethylene coated paper, whether made by laminating polyethylene film to paper or by an extrusion coating process. For gas sterilisation purposes it is necessary to have the coating on the porous base material either in a discontinuous form or of such a gas permeability that the required Bendtsen porosity is achieved.

Alternatively, said other base material may be porous instead of non-porous in which case it may be a paper with a smooth finish on one surface. Such a finish may be produced by machine glazing, by supercalendering, or by glassine calendering. This

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porous material should have a porosity and maximum pore size which are not greater than those of the neutrally sized paper forming the opposite base material in the gas-sterilisable package.

5 As a further alternative in a gas-sterilisable package, the porous form of said other base material may be a non-woven fabric or paper-like material but with the same relative limitations on porosity and maximum pore size as just quoted.

#### Neutral sizing agents.

15 These agents are alkyl ketene dimers. An example of such an agent is AQUAPEL (Registered Trade Mark) ketene dimer which is marketed by the Hercules Powder Co. Ltd., of London, England.

#### Adhesives.

20 These may be heat seal compositions such as solvent-based thermoplastic coating compositions based on ethylene/vinyl acetate copolymers. Alternatively, the adhesives may be water-based dispersions of ethylene/vinyl acetate interpolymers and may contain wax or other modifiers, or the adhesive may be a hot-melt adhesive which may contain polyisobutylene and paraffin wax. The weight of adhesive coating is between 1 and 20 gms per square metre and preferably is between 2 and 10 gms per square meter in the coated area, depending on the second base material.

#### Example 1

35 Bleached kraft paper forming the one base material was neutrally sized and then machine glazed on one surface. The Bendtsen porosity was between the limits of 60—120 cc/min and the maximum pore size was not greater than 10 mym. The paper was coated all over its unglazed surface but in a discontinuous form with a heat sealable lacquer adhesive, sold under the Registered Trade Mark ADCOTE by Morton-Williams Limited, of Hounslow, Middlesex, England which is a solvent-based thermoplastic material. The adhesive was applied in a grid form by means of a gravure cylinder and then dried. The advantage of coating the paper all over its unglazed surface in a discontinuous form is that the paper may be used for packages of different sizes or sealing areas.

55 With the paper held horizontal, coated side upwards, an article to be packaged was placed on the paper and then a second base material (said other base material) in the form of a non-porous laminate of 12.5 mym polyester film/38 mym polyethylene film was placed over the article with its polyethylene film facing downwards and heat sealed along its marginal portions in a SENTINEL (registered Trade Mark) heat

sealer to the opposing paper base material to form a sealed pouch-type package containing the article. The interior of the sealed package was gas sterilised, using ethylene oxide or a known gaseous mixture of ethylene oxide and inert gas.

70 The neutral sizing agent prevented absorption of the adhesive by the paper base material both during application and subsequent heat sealing. However the relative roughness of the unglazed surface of the paper assisted the bonding of the adhesive to the paper and in the sealed package of the bond strength of the heat seal was found to be commercially acceptable. The discontinuous form of the applied adhesive made it possible to penetrate the whole area of the package with the sterilising gas. The package was then peeled open in a smooth manner and with a clean peel, i.e. without visible transfer of fibre from the rough paper surface to the polyethylene film, thereby minimising possible contamination of the sterilised article in the package. The external glazed surface of the package was suitable for good quality printing.

#### Example II

90 A paper base material (said one base material) produced as described in Example I was heat sealed to an opposing base material consisting of untreated unplasticised polyvinyl chloride film on a Sentinel heat sealer. After gas sterilisation of the interior of the sealed package, the bond strength of the heat seal was tested and found commercially acceptable. When the opposing base materials were peeled apart, they separated in a smooth and clean manner with no visible transfer of fibres from the rough surface of the paper to the polyvinyl chloride film.

#### Example III

105 A package was made as described in Example I except that the non-porous laminate was replaced by a bleached kraft paper having the same characteristics and treatment as described in the first paragraph of Example I, but without the adhesive, the said one base material being heat sealed to the unglazed surface of the said other paper base material.

#### Example IV

115 A package was made as described in Example III except that the heat sealable lacquer adhesive was coated on to the machine glazed surface of the said one base material.

#### Example V

120 Packages were made as described in Example I, Example III and Example IV respectively, except that the adhesive used

as a water-based ethylene vinyl acetate/wax dispersion thermoplastic coating sold under the Registered Trade Mark ELVAX-D by the Du Pont Company of London, England.

#### Example VI

Packages were made as described in Example I and Example III respectively, except that the heat sealable lacquer adhesive applied to the said one base material was a hot metal adhesive sold under the Registered Trade Mark LUNAMELT PS by Industrial Waxes Limited of London, England.

#### Example VII

A package was made as described in Example I except that gas sterilisation was replaced by Gamma irradiation at 5 megarads.

In Examples III—VII the bond strength of the heat seal was commercially acceptable. Furthermore, when the opposing base materials were peeled apart they separated in a smooth manner and with a clean peel.

The invention is not limited to pouch-type packages. For example the neutrally sized paper base material may be peelably heat sealed to an open top rigid container so as to close it, the container body being of thermoformed untreated unplasticized polyvinyl chloride, or cellulose acetate, or a laminate of polyethylene and untreated unplasticized polyvinyl chloride or cellulose acetate.

Instead of applying the adhesive all over

one surface of the first base material, it may be applied to the sealing areas only, in which case it need not be applied in discontinuous form.

#### WHAT WE CLAIM IS:—

1. A package comprising opposing base materials bonded together at marginal portions by means of a heat sealed adhesive and peelable apart to open the package, wherein one of the base material is neutrally sized paper as hereinbefore defined.

2. A package according to claim 1, wherein one surface of the neutrally sized paper is machine glazed and the adhesive bonds the other surface of the neutrally sized paper to the other base material.

3. A package according to claim 2, wherein the adhesive was applied all over the unglazed surface of the neutrally sized paper but in a discontinuous form to allow a sterilizing gas to pass through it.

4. A package according to claim 3, wherein the adhesive was applied in grid form or dotted form.

5. A package according to claim 1, wherein the neutrally sized paper, excluding the sizing, has a weight not less than 55g/m<sup>2</sup>, a maximum pore size not greater than 10 mμm, and a Bendtsen porosity of 60—120 cc/min.

6. A package made according to any of Examples I to VII.

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For and on behalf of the Applicants.

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